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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,445

03/26/2004

Cathleen von Lehe

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9561 7590 05/30/2008  
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EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/810,445	<b>Applicant(s)</b> LEHE ET AL.	
	<b>Examiner</b> Victor X. Nguyen	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 10,21,23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9,11-20,22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Semrad. (5,059,183).

Semrad discloses in figures 2-4, a medical device having the limitations as recited in the above listed claim, including: an elongated member 10 has opposite first at 11 and second ends (the segment from the right side of element 13), where both the first and the second ends adapted for intravascular insertion and where the first end has a different structure than the second end (see col. 3, lines 35-45 and col. 4, lines 32-47), where the elongate member comprises a catheter 20. Note that the procedure in fig.4 discloses a rolled tip at best occurred at either side of element 41 and where an assembly further has a guidewire 10.

Claims 1,4-7 and 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Broome et al (6,152,946).

Broome et al disclose in figure 21, a medical device having the limitations as recited in the above listed claim, including: an elongated member 283 has opposite first at the proximal end 288 and second ends 296, where both the first and the second ends adapted for intravascular insertion and where the first end has a different structure than the second end (see col.9, lines 50-67 and col.10, lines 1-20), where the elongate member comprises a

catheter (fig. 21), and where element 288 is considered as a delivery structure/delivery sheath and element 290 is considered as a retrieval structure/retrieval sheath, and where the delivery sheath comprises at least one sidewall port (a sidewall port occurs where a guidewire 32 exits through out fig. 21) for receiving a wire, and where the assembly further has an embolic protection device 282. As to claims 17-19, Broome discloses in figures 21 a method for positioning a catheter within a patient's blood vessel as recited in the above listed claims, including a catheter comprising an elongated member 283, where the elongate member has a first end 288, a second end 296, where the first end comprises a delivery sheath 288, the second end comprises a retrieval sheath 290, where the catheter advances over a guidewire 32.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-9,11,20 and 22 are rejected under 35 U.S.C. 103 (a) as being unpatentable over

Broome et al. (6,152,946) in view of Yurek et al (5,662,703).

Broome discloses the invention substantially as claimed. Broome is silent regarding a sheath having a second side wall port. Yurek discloses a sheath having first 112 and second sidewall port 114 see fig. 10.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Broome by constructing a sheath having first and second sidewall port as taught by Yurek for allowing a guidewire to be exit in combination with a catheter. As to claim 11, Broome teaches a rolled tip at best occurred in fig. 24.

### ***Response to Arguments***

3. Applicant's arguments filed 2/19/2008 have been fully considered but they are not persuasive. The applicant argues that Semrad reference fails to show certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., **a proximal end** being adapted for intravascular insertion) is not recited **in the rejected claim(s) 1 and 17**. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Semrad does not disclose such a medical Device comprising an elongated member having a first end and a second end both being adapted for intravascular insertion (an intended use limitation): a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is noted that Figures 2-4 of Semrad can be clearly defined an elongated member 10 has opposite first at 11 and second ends (the segment from the right side of element 13), where both the first and the second ends adapted for intravascular insertion and where the first end has a different structure than the second end (see col. 3, lines 35-45 and col. 4, lines 32-47). Furthermore, the device of

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Semrad is a medical device since it is performed in a surgical procedure (see col. 1, lines 6-14 and col. 2, lines 25-37). Applicant's arguments with regard to the discussions of Broom's 946 are still deemed not persuasive in light of the modified prior art rejection above. Applicant is asked to please refer to the modified prior art of Broom's 946 where examiner addresses applicant's concerns regarding prior art rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ho Jackie can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

Victor X Nguyen  
Examiner  
Art Unit 3734

Vn  
5/19/2008